410 IAC 1-3

Rule 3. Infectious Waste

410 IAC 1-3-1 "Bedding" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

- Sec. 1. "Bedding" means bedding that has been used for laboratory animals. (Indiana State Department of Health; 410 IAC 1-3-1; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 436; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)
- 410 IAC 1-3-2 "Carcasses, body parts, blood and body fluids, and bedding of laboratory animals" defined Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

- Sec. 2. "Carcasses, body parts, blood and body fluids, and bedding of laboratory animals" means carcasses, body parts, blood and body fluids in liquid or semiliquid form, and bedding of animals that have been intentionally or are suspected of having been exposed to pathogens in:
 - (1) research;
 - (2) production of biologicals;
 - (3) the in vivo testing of pharmaceuticals; or
 - (4) other procedures.

(Indiana State Department of Health; 410 IAC 1-3-2; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 436; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-3 "Container" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

- Sec. 3. "Container" means any portable device or material in which infectious waste is:
- (1) stored;
- (2) transported;
- (3) treated;
- (4) disposed of; or
- (5) otherwise handled.

(Indiana State Department of Health; 410 IAC 1-3-3; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 436; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-4 "Contaminated sharp" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

- Sec. 4. "Contaminated sharp" means an object that is capable of cutting or penetrating the skin and has been in contact with blood or body fluids. The term includes any of the following:
 - (1) Hypodermic or suture needle.
 - (2) Syringe.
 - (3) Scalpel blade.

- (4) Pipette.
- (5) Lancet.
- (6) Broken glass.

(Indiana State Department of Health; 410 IAC 1-3-4; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-5 "Communicable disease" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-2-1

Sec. 5. "Communicable disease" means a communicable disease as defined by rule under IC 16-41-2-1. (Indiana State Department of Health; 410 IAC 1-3-5; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-5.5 "Department" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 5.5. "Department" means the Indiana state department of health. (Indiana State Department of Health; 410 IAC 1-3-5.5; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-6 "Emergency medical services provider" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-31-3

Sec. 6. "Emergency medical services provider" means a person certified under IC 16-31-3. (Indiana State Department of Health; 410 IAC 1-3-6; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1382; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-7 "Facility" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-21-2; IC 16-28-1; IC 16-41-12; IC 16-41-16

Sec. 7. "Facility" means any of the following places where infectious waste activity occurs:

- (1) Hospital.
- (2) Ambulatory surgical center as defined in IC 16-21-2.
- (3) Medical/diagnostic laboratory.
- (4) Blood center as defined in IC 16-41-12.
- (5) Pharmaceutical company.
- (6) Academic research laboratory company.
- (7) Industrial research laboratory.
- (8) Health facility as defined in IC 16-28-1.
- (9) Office and mobile units of a health care provider.
- (10) Diet or health care clinic.
- (11) Office of a veterinarian.
- (12) Veterinary hospital.
- (13) Emergency medical services provider.
- (14) Mortuary.

(Indiana State Department of Health; 410 IAC 1-3-7; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-8 "Health care provider" defined

Authority: IC 16-19-3-4; IC 16-41-16-8 Affected: IC 16-18-2-163; IC 16-41-16

Sec. 8. "Health care provider" means a person employed as, or by, or receiving training from, a provider as defined in IC 16-18-2-163, or by a laboratory, blood center, state institution, or any other facility where the person is likely to have direct contact with blood or body fluids. (*Indiana State Department of Health;* 410 IAC 1-3-8; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 437; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-9 "Infectious waste activity" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 9. "Infectious waste activity" means the:

- (1) generation;
- (2) collection;
- (3) storage;
- (4) transportation;
- (5) treatment; or
- (6) disposal of infectious waste;

as defined in this rule. (Indiana State Department of Health; 410 IAC 1-3-9; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-10 "Infectious waste" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

- Sec. 10. (a) "Infectious waste", except as provided in subsection (b), means waste that epidemiologic evidence indicates is capable of transmitting a dangerous communicable disease. The term includes, but is not limited to, the following:
 - (1) Contaminated sharps or contaminated objects that could potentially become contaminated sharps.
 - (2) Infectious biological cultures, infectious associated biologicals, and infectious agent stock.
 - (3) Pathological waste.
 - (4) Blood and blood products in liquid and semiliquid form.
 - (5) Carcasses, body parts, blood and body fluids in liquid and semiliquid form, and bedding of laboratory animals.
 - (6) Other waste that has been intermingled with infectious waste.
- (b) The term, as it applies to a home health agency or to services delivered in the home of a hospice patient, includes only contaminated sharps. (Indiana State Department of Health; 410 IAC 1-3-10; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-11 "Mortuary" defined

Authority: IC 16-19-3-4; IC 16-41-16-8 Affected: IC 16-41-16; IC 25-15-2-15 Sec. 11. "Mortuary" means a funeral home as defined in IC 25-15-2-15. (Indiana State Department of Health; 410 IAC 1-3-11; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-12 "Pathological waste" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 12. "Pathological waste" means:

- (1) tissues;
- (2) organs;
- (3) body parts; and
- (4) blood or body fluids in liquid or semiliquid form of humans;

that are removed during surgery, biopsy, or autopsy. (Indiana State Department of Health; 410 IAC 1-3-12; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-13 "Person" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 13. "Person" means any:

- (1) individual;
- (2) facility;
- (3) partnership;
- (4) copartnership;
- (5) firm;
- (6) company;
- (7) association;
- (8) joint-stock company;
- (9) corporation;
- (10) governmental entity; or
- (11) agent.

(Indiana State Department of Health; 410 IAC 1-3-13; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-14 "Secured area" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 14. "Secured area" means an area that is designed and maintained to prevent the entry of unauthorized persons. (Indiana State Department of Health; 410 IAC 1-3-14; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1383; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-15 "Semiliquid blood and blood products" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 15. "Semiliquid blood and blood products" means blood and blood products that have intermediate fluid properties and are capable of flowing in a manner similar to a liquid. (*Indiana State Department of Health; 410 IAC 1-3-15; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 438; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 1-3-16 "State board" defined (Repealed)

Sec. 16. (Repealed by Indiana State Department of Health; filed Sep 18, 1998, 11:38 a.m.: 22 IR 440)

410 IAC 1-3-17 "Storage" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 17. "Storage" means the containment of infectious waste in such a manner as not to constitute:

- (1) collection;
- (2) treatment;
- (3) transport; or
- (4) disposal.

(Indiana State Department of Health; 410 IAC 1-3-17; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-18 "Veterinarian" defined

Authority: IC 16-19-3-4; IC 16-41-16-8 Affected: IC 15-5-1.1; IC 16-41-16

Sec. 18. "Veterinarian" means a person authorized to practice veterinary medicine under IC 15-5-1.1. (Indiana State Department of Health; 410 IAC 1-3-18; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-19 "Waste" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 19. "Waste" means any solid, liquid, or semiliquid material that:

- (1) is discarded or being accumulated prior to being discarded; or
- (2) has served its natural, biological, medical, or intended purpose and is generally discarded and not reused.

(Indiana State Department of Health; 410 IAC 1-3-19; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-20 "Waste handlers" defined

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 20. "Waste handlers" means any person who handles infectious waste. (Indiana State Department of Health; 410 IAC 1-3-20; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-21 Applicability of standards

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-11

- Sec. 21. (a) This rule applies, without regard to quantity, to defined facilities and persons involved in infectious waste activity.
 - (b) This rule represents minimum standards, and persons may utilize more stringent standards.
- (c) All written policies required under this rule shall, at a minimum, comply with the requirements of IC 16-41-11. (Indiana State Department of Health; 410 IAC 1-3-21; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-22 Appropriate containment and labeling; effective treatment, transport, or disposal

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 22. For purposes of IC 16-41-16 and this rule, the generator of infectious waste is responsible for the appropriate containment, appropriate labeling, effective treatment, transport, and disposal of infectious waste as required by this rule. A person may provide services to the generator of infectious waste, including the appropriate containment, appropriate labeling, effective treatment, transport, or disposal of infectious waste. Both the generator of infectious waste and the person providing services to the generator of infectious waste are responsible for complying with the requirements set forth in this rule. (Indiana State Department of Health; 410 IAC 1-3-22; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-23 Written policies, procedures

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16-9

Sec. 23. All persons and facilities subject to this rule shall:

- (1) have a written policy and procedures that, at a minimum, contain:
 - (A) the requirements contained in this rule; and
 - (B) the sanctions, including discipline and dismissal of persons, if warranted, for failure to follow the requirements set forth in this rule;
- (2) provide necessary instruction and materials, including protective garments, to implement this rule prior to giving a person an assignment where contact with infectious waste is likely;
- (3) maintain a record of such instruction, including an attendance record of a person's participation in the instruction: and
- (4) make all records available to the department for inspection under IC 16-41-16-9.

(Indiana State Department of Health; 410 IAC 1-3-23; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1384; filed Sep 18, 1998, 11:38 a.m.: 22 IR 439; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-24 Containment

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 24. (a) All persons and facilities subject to this rule shall ensure that infectious waste is at all times contained in a manner that will reasonably protect waste handlers and the public from contracting dangerous communicable disease that may result from exposure to the infectious waste.

- (b) All persons and facilities subject to this rule shall place contaminated sharps or contaminated objects that could potentially become contaminated sharps, infectious biological cultures, infectious associated biologicals, and infectious agent stock in containers that are:
 - (1) leak proof, rigid, puncture-resistant;
 - (2) tightly sealed to prevent expulsion;
 - (3) labeled with the biohazard symbol; and
 - (4) effectively treated in accordance with this rule prior to being stored in an unsecured area and sent for final disposal.
- (c) All persons and facilities subject to this rule shall place pathological waste; laboratory animal carcasses, laboratory animal body parts, laboratory animal blood and body fluids, and laboratory animal bedding; human blood; human blood products in liquid or semiliquid form; and human body fluids that are visibly contaminated with blood in containers that are:
 - (1) impervious to moisture;
 - (2) sufficient strength and thickness to prevent expulsion;
 - (3) secured to prevent leakage or expulsion;
 - (4) labeled with the biohazard symbol; and
 - (5) effectively treated in accordance with this rule prior to being placed in an unsecured area and sent for final disposal.

(Indiana State Department of Health; 410 IAC 1-3-24; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1385; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-25 Storage

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 25. If infectious waste is stored prior to final disposal, all persons subject to this rule shall:

- (1) store infectious waste in a secure area that:
 - (A) is locked or otherwise secured to eliminate access by or exposure to the general public;
 - (B) affords protection from adverse environmental conditions and vermin; and
 - (C) has a prominently displayed biohazard symbol;
- (2) store infectious waste in a manner that preserves the integrity of the container, and is not conducive to rapid microbial growth and putrefaction; and
- (3) disinfect reusable containers for infectious waste each time that they are emptied, unless the surfaces of the reusable containers have been protected from contamination by disposable liners, bags, or other devices that are removed with the infectious waste.

(Indiana State Department of Health; 410 IAC 1-3-25; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1385; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-26 Treatment

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 26. (a) All persons and facilities subject to this rule shall either effectively treat infectious waste in accordance with this rule or transport infectious waste off-site for effective treatment in accordance with this rule.

(b) A treatment is effective if it reduces the pathogenic qualities of infectious waste for safe handling, is designed for the specific infectious waste involved, and is carried out in a manner consistent with this rule. Effective treatment may include:

- (1) incineration:
- (2) steam sterilization:
- (3) chemical disinfection;
- (4) thermal inactivation;
- (5) irradiation; or
- (6) discharge in a sanitary sewer or septic system that is properly installed and operating in accordance with state and local laws.
- (c) Except as provided in section 28 of this rule, all persons and facilities subject to this rule may store, transport, and dispose of infectious waste that has been effectively treated in accordance with this rule in the usual manner for waste that is noninfectious. (*Indiana State Department of Health; 410 IAC 1-3-26; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1385; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234*)

410 IAC 1-3-27 Protection in transport

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 27. All persons and facilities subject to this rule shall:

- (1) transport infectious waste in a manner that reasonably protects waste handlers and the public from contracting dangerous communicable disease; and
- (2) effectively treat infectious waste in accordance with this rule before it is compacted.

(Indiana State Department of Health; 410 IAC 1-3-27; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1385; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-28 Transporting off-site

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16

Sec. 28. (a) All persons and facilities subject to this rule who are transporting infectious waste off-site, whether effectively treated or not, shall:

- (1) mark containers of infectious waste with a label that states the name, address, and telephone number of the generating facility and treatment facility, if applicable; and
- (2) provide a form that contains:
 - (A) the name, address, and telephone number of the generating facility and treatment facility, if applicable;
 - (B) a brief description of the waste and the method of effective treatment; and
 - (C) the signature of a responsible person.

(b) The information required in subsection (a) may be enclosed between the secondary packaging and the outer packaging, when such packaging is used. The outer packaging must contain a biohazard symbol. (Indiana State Department of Health; 410 IAC 1-3-28; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1386; filed Sep 18, 1998, 11:38 a.m.: 22 IR 440; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 1-3-29 Penalties for violation

Authority: IC 16-19-3-4; IC 16-41-16-8

Affected: IC 16-41-16-10

Sec. 29. Penalties for violation of this rule are set forth in IC 16-41-16-10. (Indiana State Department of Health; 410 IAC 1-3-29; filed Jan 17, 1989, 3:30 p.m.: 12 IR 1386; filed Sep 18, 1998, 11:38 a.m.: 22 IR 440; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)